IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION, *Plaintiff*, v. MEDTRONIC VASCULAR, INC., BOSTON SCIENTIFIC CORP. and SCIMED LIFE SYSTEMS, INC., *Defendants*.	)	C.A. No. 97-550-SLR (Consolidated)
BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC., *Plaintiffs*, v. ETHICON, INC., et al., *Defendants*.	)	C.A. No. 98-19-SLR

CORDIS' ANSWERING BRIEF IN OPPOSITION TO BSC'S MOTIONS FOR JMOL OR A NEW TRIAL ON INFRINGEMENT AND VALIDITY OF CLAIM 23 OF THE PALMAZ '762 PATENT

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INTRODUCTION

Prior to and during the retrial, BSC admitted that for purposes of this retrial, there was only one infringement issue – infringement of "substantially uniform thickness." The proof at trial was overwhelming that the wall of the NIR stent literally has a "substantially uniform thickness" under the Court's claim construction. Unchallenged evidence showed that the NIR is made from a metal sheet whose uniform thickness is not altered in the manufacturing process – resulting in a wall thickness that is remarkably uniform, as confirmed by measurements made by BSC engineers. BSC's assertion to the contrary rested on its improper and misleading attempt to confuse "wall surface" with "substantially uniform thickness," and to confuse *thickness* with *height* by measuring metal-plus-air and treating that as the wall's thickness. The jury properly rejected BSC's assertions on the evidence presented.

As to obviousness, Cordis demonstrated that the Ersek '744 patent, which was BSC's primary reference, describes a staple-like device for conventional open surgery that is different from the device of claim 23 in ways that are numerous and fundamental. The prior art did not provide any motivation to alter Ersek to lessen those significant differences. Moreover, the objective evidence of long-felt need, skepticism, commercial success and praise for the invention – standing alone – was powerful enough to defeat BSC's obviousness defense. The jury properly rejected BSC's obviousness defense on the evidence presented.

The jury reached its verdict after both sides presented their evidence in a fair trial that was not tainted by error. Overwhelming evidence supports the verdict in Cordis' favor. There is no basis for granting JMOL or a new trial.

THE LEGAL STANDARDS GOVERNING POST-TRIAL MOTIONS FOR JMOL

In order to obtain JMOL following a jury verdict, a verdict loser must show that "the record is critically deficient of that minimum quantity of evidence from which a jury might reasonably afford relief." Trabal v. Wells Fargo Armored Serv. Corp., 269 F.3d 243, 249 (3d Cir. 2001). The Court must "view[] the evidence in the light most favorable to the [verdict winner] and giv[e] it the advantage of every fair and reasonable inference ...." Gagliardo v. Connaught Labs., Inc., 311 F.3d 565, 568 (3d Cir. 2002) (citation omitted).

> To prevail on a renewed motion for judgment as a matter of law following a jury trial under Federal Rule of Civil Procedure 50(b), the moving party "'must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusions implied [by] the jury's verdict cannot in law be supported by those findings.'" Pannu v. Iolab Corp., 155 F. 3d 1344, 1348 (Fed. Cir. 1998) (quoting Perkin-Elmer Corp. v. Computervision Corp., 732 F. 2d 888, 893 (Fed. Cir. 1984)). "'Substantial' evidence is such relevant evidence from the record taken as a whole as might be acceptable by a reasonable mind as adequate to support the finding under review." Perkin-Elmer Corp., 732 F. 2d at 893. In assessing the sufficiency of the evidence, the court must give the non-moving party, "as [the] verdict winner, the benefit of all logical inferences that could be drawn from the evidence presented, resolve all conflicts in the evidence in his favor, and in general, view the record in the light most favorable to him." Williamson v. Consol. Rail Corp., 926 F. 2d 1344, 1348 (3d Cir. 1991); Perkin-Elmer Corp., 732 F. 2d at 893. The court may not determine the credibility of the witnesses nor "substitute its choice for that of the jury between conflicting elements of the evidence." Id. In summary, the court must determine whether the evidence reasonably supports the jury's verdict. See Dawn Equip. Co. v. Kentucky Farms Inc., 140 F. 3d 1009, 1014 (Fed. Cir. 1998).

Arthrocare Corp. v. Smith & Nephew, Inc., 310 F. Supp. 2d 638, 652 (D. Del. 2004).

THE LEGAL STANDARDS GOVERNING NEW TRIAL MOTIONS

"The decision to grant or deny a new trial is [committed to] the sound discretion of the trial court ...." Arthrocare, 310 F. Supp. 2d at 652. "The court, however, must be proceed cautiously and not substitute its own judgment of the facts and assessment of the witnesses' credibility for the jury's independent evaluation." Id. at 653.

Where a motion for a new trial is based on a purported trial error, the court must consider: "'(1) whether an error was in fact committed, and [if so] (2) whether that error was so prejudicial that denial of a new trial would be 'inconsistent with substantial justice.'" Arthrocare, 310 F. Supp. 2d at 666, quoting Finch v. Hercules, Inc., 941 F. Supp. 1395, 1414 (D. Del. 1996).

I. INFRINGEMENT OF "SUBSTANTIALLY UNIFORM THICKNESS"

A. BSC is Not Entitled to JMOL

Following a jury verdict, courts give "substantial deference" to the jury's "factual application of a claim construction to the accused device in an infringement determination." Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1312 (Fed. Cir. 2003). "Viewing the evidence in the light most favorable to the [verdict winner] and giving it the advantage of every fair and reasonable inference," there was ample evidence from which the jury here "could reasonably find liability." Gagliardo, 311 F. 3d at 568.

1. The Verdict is Supported by Substantial Evidence

Before and during the retrial, BSC conceded that infringement of all limitations other than "substantially uniform thickness" was not in dispute for purposes of the retrial. E.g., D.I. 1310 at 2; 3/21/05 Tr. 821:9-13; 3/22/05 Tr. 832:9-833:11. The only disputed limitation was "substantially uniform thickness." The Court defined that limitation as follows (3/23/05 Tr. 1351:9-13):

> The wall of a tubular member must be of largely or approximately uniform thickness. A wall that varies in thickness by as much as 100 percent cannot be said to be of substantially uniform thickness.

To meet this limitation, the thickness of the wall of the tubular member only needs to be "*substantially* uniform" – not perfectly uniform. A stent has a "substantially uniform thickness" under the Court's claim construction if its wall thickness is "largely or approximately uniform." 3/23/05 Tr. 1351:9-13.

Under the Court's claim construction, it is the "wall" of the tubular member that must have a "substantially uniform thickness." 3/23/05 Tr. 1351:9-13. Because the wall is the metal that makes up the stent, the thickness of the wall is equal to the thickness of the metal. As Dr. Buller explained, "[t]he walls are the metal of the stent." 3/18/05 Tr. 429:7; see also 3/18/05 Tr. 426:18-23, 427:7-23. BSC's expert Dr. Kobi Richter agreed that "the metal is what defines the wall." 3/22/05 Tr. 848:17-22.

This testimony – by Cordis' expert and by Dr. Richter – is consistent with the '762 specification. The specification equates the thickness of the "wall surface" with the thickness of the struts when it states that the stent can expand uniformly because, *inter alia*, "the thickness of the wall surface 74, or the thickness of connecting members 77, elongate members 75, and members 78, 79 is the same uniform thickness." PX 3 at 7:26-33. Moreover, the specification teaches that the purpose of a uniform wall thickness is to allow for uniform expansion. PX 3 at 7:26-33. As Dr. Buller explained, what should expand uniformly is "the metal of the stent, if it's made from metal." 3/18/05 Tr. 427:19-20; see also 3/18/05 Tr. 426:9-427:23.

As Dr. Buller testified, the NIR stent has a uniform wall thickness because the wall of the NIR, i.e., the metal that makes up the stent, has "the same metal thickness." 3/18/05 Tr. 429:12. Dr. Richter agreed that "[t]he thickness of the metal that the stent is made of" is the "same or very close to being the same [throughout the stent]." 3/22/05 Tr. 850:19-23.

It is not surprising that the NIR's wall has a substantially uniform thickness. After all, the NIR is made from a "flat sheet of metal" of uniform thickness. 3/18/05 Tr. 432:17-18 (Buller); see also 3/22/05 Tr. 851:4-7 (Richter); 3/18/05 Tr. 452:19-21. The manufacturing steps used in making the NIR do not alter the metal's uniform thickness. 3/18/05 Tr. 433:19-23. As a result, the "walls of the tubular member are of a substantially uniform thickness" after the sheet is rolled into a cylinder and the ends are welded. 3/18/05 Tr. 437: 9-12. Dr. Richter agreed that the manufacturing process does not alter the metal's "uniform thickness" and that its uniform thickness "stays the same." 3/22/05 Tr. 851:4-18.

The chapter on the NIR in the *Handbook of Coronary Stents*, co-authored by Dr. Richter, confirms this. It reports that the metal that makes up the NIR's wall has a thickness of 0.004 inch (rounded to the nearest thousandths of an inch). 3/18/05 Tr. 438:4-439:24; PX 7207. It does not report any variation in the wall's thickness because there is none. Instead, as Dr. Buller explained, it treats the NIR's thickness as "the same thickness all over the stent." 3/18/05 Tr. 439:22-24.

Measurements of wall thickness that BSC engineers made for purposes of this case show that the NIR has a miniscule standard deviation of only six hundred-thousandths of an inch (0.00006 inch) from an average "wall thickness" of 0.00366 inch. 3/18/05 Tr. 440:6-442:9; see also PX 7236. As Dr. Buller explained, this minuscule level of deviation makes the NIR "an incredibly uniform device," Tr. 442:9, and shows that the wall "has very little variation." 3/18/05 Tr. 443:8-10. "It's substantially uniform." 3/18/05 Tr. 443:8.

At trial, BSC took the position that two artifacts of the manufacturing process prevent the NIR from having a "substantially uniform thickness": (1) the tiny welds that are applied to hold the stent together after the flat sheet is rolled into a cylinder; and (2) the slight

protrusion of the NIR's U-loops when the sheet is rolled into a cylinder. Dr. Buller explained that neither feature is a departure from a "substantially uniform thickness."

The NIR stent has only a few welds, which are aligned in a row where the opposite ends of the metal sheet are joined. The number of welds varies depending on the length of the stent. The welds occupy only a "tiny part" of the NIR's total surface area, 3/18/05 Tr. 457:23-24, on the order of 2% of the total surface area, 3/18/05 Tr. 443:14-444:1, and they are too small to detract from a "substantially uniform thickness." Under the Court's claim construction, "[a] wall that varies in thickness by as much as 100 percent cannot be said to be of substantially uniform thickness," 3/23/05 Tr. 1351:9-13, but even at their most extreme, the welds vary far less than that. At their thickest points, the welds represent at most a 74 percent variation in thickness. 3/18/05 Tr. 444:6-13. This is "nowhere near to a hundred-percent [variation in] thickness." 3/18/05 Tr. 458:22-23. The welds do not prevent the NIR from having a thickness that "largely or approximately uniform." 3/18/05 Tr. 457:12-458:10.

As for the U-loops, the thickness of the metal is the same at the U-loops as everywhere else (apart from the welds, which are discussed above). Although the U-loops "protrude a tiny amount" when the flat sheet is rolled to form a cylindrical stent, 3/18/05 Tr. 458:16-24, this protrusion has nothing to do with the U-loops' "thickness." Dr. Buller so testified (3/18/05 Tr. 459:10-21):

> Q. … [D]oes the fact that U sticks out slightly have any bearing on the thickness of the walls of the NIR stent?
>
> A. It has absolutely no bearing on the thickness. … [T]hey do protrude a very small amount … but they are of exactly the same thickness. ***This [protrusion] does not alter the thickness. The thickness of the metal here is exactly the same at the tip of the U.*** (Emphasis added).

BSC's argument on this point confused the U-loops' *thickness* with their *height*. What BSC characterized as the U-loops' "thickness" was really the thickness of the wall (i.e., the metal) plus a measurement of the empty space or air under the U-loops where they protrude, in other words, their height. As BSC's engineering expert Dr. Snyder conceded on cross-examination, "***I measured heights*** out of proper orientation from the defined plane [for the U-loops] ***and I compared it to the thickness*** of the original metal [at the C-loops], yes." 3/22/05 Tr. 979:19-24 (emphasis added). A careful review of BSC's documents did not reveal any documents that would support this approach, 3/18/05 Tr. 443:11-24 (Buller), and Dr. Snyder could not recall any BSC documents that would support it. 3/22/05 Tr. 989:3-14.

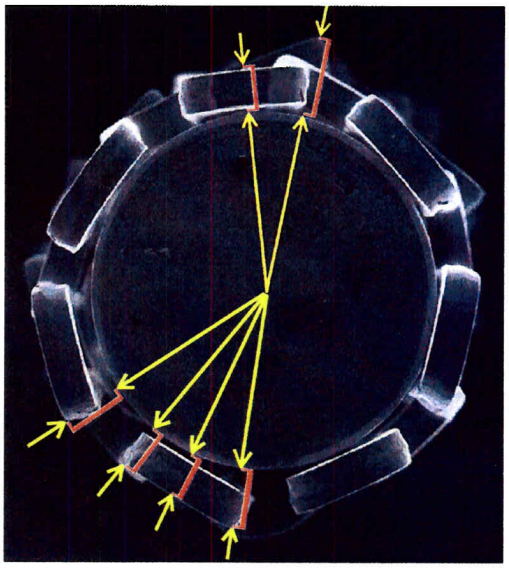
By confusing the U-loops' thickness with their height (or protrusion), BSC was able to pretend that there is a variation in thickness where none exists. This game was exposed when Dr. Richter conceded on cross-examination that in measuring "thickness," BSC was measuring air as well as metal:

> Q. .... [I]n doing your measurement of the thickness of the wall, you're including air in your measurement, aren't you?
>
> A. Correct.

3/22/05 Tr. 852:4-7. Dr. Snyder also conceded that he was including "air underneath the U struts" in his measurements of thickness. 3/22/05 Tr. 982:21-24.

BSC's ruse was further exposed during Dr. Snyder's cross-examination. Dr. Snyder readily agreed that Cordis' counsel's hand was about an inch thick. But when counsel positioned his hand so that it was one foot above the floor (thus changing its height), Dr. Snyder refused to say whether his hand was still an inch thick. 3/22/05 Tr. 977:16-978:17. Dr. Snyder protested that this simple question – "Is my hand still an inch thick?" – was a "trick question."

3/22/05 Tr. 978:7-10. But the real trick was the one BSC tried to play on the jury, by confusing the U-loops' height with their thickness.



The photograph on the right (DXB-15067, with yellow and red lines added) illustrates the error in BSC's approach. As this photograph shows, the metal that makes up the NIR stent, i.e., the wall, has a rectangular cross-section of uniform thickness. BSC ignored that uniform thickness. Instead, BSC measured metal-plus-air, indicated by the red lines, and it used those measurements to confuse the metal's *thickness* with the *height* of its outer surface from an (imaginary) internal cylinder.

The jury was entitled to reject that approach as an improper way to measure wall thickness. Experts for both sides testified that "[t]he walls are the metal of the stent," 3/18/05 Tr. 429:7 (Buller), and that the metal "is what defines the [stent's] wall." 3/22/05 Tr. 848:17-22 (Richter). In addition, both sides' experts agreed that the NIR is made from a flat metal sheet whose uniform thickness is not altered in the manufacturing process. 3/18/05 Tr. 437:9-12 (Buller); 3/22/05 Tr. 851:4-18 (Richter). In addition, measurements by BSC engineers confirm that the NIR's wall thickness varies by a standard deviation of only six hundred-thousandths of an inch (0.00006 inch) from perfect uniformity, 3/18/05 Tr. 440:6-442:9, PX 7236, making the NIR "an incredibly uniform device." 3/18/05 Tr. 442:9. "Viewing the evidence in the light most favorable to the [verdict winner] and giving it the advantage of every fair and reasonable inference," Gagliardo, 311 F. 3d at 568, there was ample evidence from which a reasonable jury

could find that the NIR has a "substantially uniform thickness" under the Court's claim construction.

2. As This Court Has Held, the Federal Circuit's Decision Does Not Require Measuring Thickness the Way BSC Would Like to Measure It

BSC argues (D.I. 1395 at 5-6) that under the Federal Circuit's decision in Cordis Corp. v. Medtronic AVE, Inc., 339 F.3d 1352 (Fed. Cir. 2003), the only proper way to measure wall thickness is the method used by BSC's experts, which involves measuring metal-plus-air, or as BSC puts it, measuring the "radial distance between the outer surface of the … stent and an inner cylinder that would fit inside the stent." D.I. 1395 at 10.

Prior to the trial, this Court rejected the same argument when AVE raised it. The Court held in its March 1, 2005 Order that ***"[t]he appropriate test for measuring the thickness of the wall surface … is a question of fact for the jury, not a matter of law determined by the Federal Circuit."*** D.I. 1337 [2/28/05 Order] at 5-6 (emphasis added). The Court further held that ***"the Federal Circuit's discussion with respect to measuring the thickness of a strut does not amount to a holding that one of ordinary skill would only measure thickness [in] a certain way."*** Id. (emphasis added). The Court concluded that ***"each party can present evidence with respect to how one of ordinary skill in the art would measure the thickness of the wall surface."*** Id. (emphasis added).

Contrary to BSC's contention, the Federal Circuit did not hold that thickness must be measured "only … in a certain way." Id. Rather, its decision treats the method of measuring the thickness as a "a question of fact for the jury," id., to be determined based on expert testimony, not by the application of legal rules. BSC misreads the decision in Cordis v. AVE, 339 F.3d 1352, and this Court's February 28, 2005 Order, when it argues otherwise. The jury heard the testimony of both sides' experts on this "question of fact," D.I. 1337 at 5-6, and it chose

to accept Cordis' evidence and reject BSC's evidence. There is no basis for overturning that verdict. See Gagliardo, 311 F.3d at 568; Arthrocare, 310 F. Supp. 2d at 652.

BSC further argues (D.I. 1395 at 12) that it would be wrong to equate a stent's wall thickness with the thickness of its struts. The '762 specification teaches the opposite. The specification equates the thickness of the "wall surface" with the thickness of the struts that form the wall surface. In particular, it states that uniform expansion is achieved, *inter alia*, because "the thickness of the wall surface 74, or the thickness of connecting members 77, elongate members 75, and members 78, 79 is the same uniform thickness." PX 3 at 7:26-33. As the specification explains, Fig. 2 of the '762 patent illustrates the struts' "uniform thickness," as well as their "preferred cross-sectional configuration … which configuration is rectangular." Id. at 7:34-37. Photographs in evidence show that the struts of the NIR stent have the same uniform rectangular cross-section, and the same "uniform thickness," as the Fig. 2 embodiment. See, e.g., DXB-15067, DXB-15069, DXB-15070.

Fig. 2

The jury considered the evidence and was entitled to conclude that the NIR's wall thickness can appropriately be measured in the way the '762 patent teaches, i.e., by measuring the thickness of the material that makes up the stent's wall. There is no basis for disturbing that conclusion. Gagliardo, 311 F.3d at 568; Arthrocare, 310 F. Supp. 2d at 652.

3. BSC's "Prosecution History Disclaimer" Argument is at Odds with the Federal Circuit's Reading of the File History

BSC also offers what is in essence a claim construction argument, that Cordis "disavowed" devices "in which the struts have twisted out of the plane of the starting material" when it distinguished Ersek in the reexamination. D.I. 1395 at 9. The Federal Circuit considered the same file history and drew a different conclusion.

The Federal Circuit reviewed the portions of the '762 reexamination on which BSC relies. See Cordis, 339 F.3d at 1360-62. It concluded that "Cordis's basis for distinguishing Ersek appears to have been that Ersek's walls were at least twice as thick at the intersections of strands [i.e., the bridges] as along the strands themselves." Cordis, 339 F.3d at 1361. The Federal Circuit found that Cordis distinguished Ersek's non-uniform thickness by "focus[ing] on the double thickness of the bridge portions of Ersek's walls." Id.; see also id. at 1362 ("Cordis thus focused on the double thickness of the bridge portions of the Ersek device"). Based on the file history, the Federal Circuit held that Cordis had "disclaimed coverage of any device with a variation [in thickness] of at least 100 percent." Id. at 1362. It did not find any other disclaimer. BSC invites error when it advocates a reading of the file history and a claim construction at odds with the Federal Circuit's decision.

4. BSC Confuses "Substantially Uniform Thickness" with "Wall Surface"

Infringement of "wall surface" was resolved in Cordis' favor in 2000 when the first BSC jury rendered its verdict of infringement. BSC was not granted a new trial on infringement of that limitation and it was properly not part of the retrial of this case. Before the trial, BSC acknowledged this. BSC stipulated in the Joint Pretrial Order (D.I. 1310, Tab 1 at 2):

> ***For purposes of this trial, it is admitted that the NIR stent meets each of the limitations of claim 23 of the '762 patent***, either literally or under the doctrine of equivalents, ***except for*** the ***"substantially uniform thickness"*** limitation. (Emphasis added).

BSC's trial strategy was aimed at un-doing this admission. Its theory at trial – repeated in its JMOL motion – was that wall thickness must be measured by calculating the "radial distance between the outer surface of the … stent and an inner cylinder that would fit inside the stent." D.I. 1395 at 10. That approach misapprehends "substantially uniform thickness," and improperly confuses "wall surface" and "substantially uniform thickness."

As construed by this Court, the "wall surface" limitation requires that "[t]he outer surface of the tubular member must be disposed in a common cylindrical plane." 3/23/05 Tr. 1351:6-8. Under that construction, the "wall surface" limitation addresses *where* the "outer surface" of the tubular member is "disposed" (i.e., placed or arranged).

In contrast, the "substantially uniform thickness" limitation addresses the wall's thickness – not the location of its outer surface and not the distance between its outer surface and an imaginary inner cylinder. BSC misapprehends the "substantially uniform thickness" limitation – and confuses "uniform thickness" with "wall surface" – when it argues otherwise.

Under the Court's February 28, 2005 Order, the appropriate way to measure the wall's "substantially uniform thickness" is "a question of fact for the jury, not a matter of law …." D.I. 1337 at 5-6. The jury heard both sides' evidence and accepted Cordis' position. "Viewing the evidence in the light most favorable to the [verdict winner] and giv[e] it the advantage of every fair and reasonable inference …," Gagliardo, 311 F.3d at 568, there is no basis for disturbing that verdict. Id.; Arthrocare, 310 F. Supp. 2d at 652.

B. BSC is Not Entitled to a New Trial on Infringement of "Substantially Uniform Thickness"

After two jury trials in which it was twice found to infringe the "substantially uniform thickness" limitation, BSC now asks for a third trial on that issue. However, BSC received a fair trial that was not tainted by error. It cannot show that there would be a "'miscarriage of justice … if the verdict were to stand.'" Olefins Trading, Inc. v. Han Yang Chem. Corp., 9 F.3d 282, 289-90 (3d Cir. 1993), quoting Fineman v. Armstrong World Indus., Inc., 980 F.2d 171, 211 (3d Cir. 1992). Its new trial motion has should be denied.

1. The Court Did Not Err in Instructing the Jury that Infringement of "Wall Surface" Was Not in Dispute in the Retrial

BSC disregards its own stipulations and concessions when it argues (D.I. 1395 at 16) that it was "extremely prejudicial" to instruct the jury that infringement of "wall surface" was not in dispute in this trial. If anything, the challenged instruction was more neutral than BSC's own stipulation that infringement of every limitation except for "substantially uniform thickness" was admitted for purposes of this trial. BSC's stipulation defeats its current argument.

BSC admitted or stipulated to the key facts on at least three occasions, before and during the trial. The first such stipulation was in the Joint Pretrial Order, where BSC agreed:

> ***For purposes of this trial, it is admitted that the NIR stent meets each limitation of claim 23 of the '762 patent, either literally or under the doctrine of equivalents, except for the "substantially uniform thickness" limitation.***

D.I. 1310 Tab 1 at 2 (emphasis added).

The second such stipulation was during the trial, when BSC's counsel conceded that ***"[f]or purposes of this trial, the only issue is whether or not the substantially uniform thickness limitation is met. The others are not in dispute."*** 3/21/05 Tr. 821:9-13 (emphasis added).

The third stipulation also came during the trial, when BSC stipulated to a curative instruction on this issue. The need for a curative instruction arose near the end of the first day of Dr. Richter's testimony, when he refused to agree on cross-examination that "in this case ... there's no dispute that, under Claim 23, the NIR stent has a plurality of slots." 3/21/05 Tr. 819:18-25. This attempt to dispute infringement of "slots" necessitated an early recess. 3/21/05 Tr. 820:1-13.

Before trial resumed the following morning, the parties agreed on a curative instruction and an agreed upon question-and-answer for Dr. Richter – both of which are identical

in substance to the instruction BSC now attacks as prejudicial error. Counsel summarized the parties' stipulation before Dr. Richter's testimony resumed:

> MR. DISKANT: I think we've reached a substantial number of agreements.
>
> First, the parties have agreed on an instruction to request your Honor to give at the beginning of the testimony. .... ***The proposed curative instruction is***:
>
> In light of yesterday's testimony [by Dr. Richter], ***I want to instruct you that there is only one infringement issue for you to decide in this case. That is the question of whether the NIR stent meets the substantially uniform thickness limitation of Claim 23 of the '762 patent.***
>
> ***We've then agreed that Mr. Cavanaugh will ask just one question on the subject of Dr. Richter, and that question will be***, in substance:
>
> Dr. Richter, ***you understand that the only infringement issue in this case is whether the NIR stent meets the substantially uniform thickness limitation of Claim 23***.
>
> ***He will just say yes***. .... If that's acceptable to your Honor, ***the parties have agreed on that.***
>
> MR. BADENOCH: ***That is acceptable, your Honor.***

3/22/05 Tr. 832:9-833:11. With the agreement of both sides, the Court then gave the curative instruction on which the parties had agreed. 3/22/05 Tr. 847:11-19. That instruction was followed by the question-and-answer that the parties had agreed upon before testimony resumed (3/22/05 Tr. 848:5-11):

> Q. Dr. Richter, following up on the instruction Judge Robinson just gave, you understand that the only infringement issue for the jury to decide in this case is whether the NIR stent meets the substantially uniform thickness limitation of Claim 23 of the '762 patent?
>
> A. .... Yes, I do.

The instruction BSC now complains of – that "the 'wall surface' limitation is not in dispute in this case" and that "[t]he only limitation in dispute in this case is the 'substantially uniform thickness' limitation" (D.I. 1403) – is identical in substance to its counsel's concession that "[f]or purposes of this trial, the only issue is whether or not the substantially uniform thickness limitation is met. The others are not in dispute." 3/21/05 Tr. 821:9-13. If anything, the challenged instruction did not go as far as BSC's stipulation that "[f]or purposes of this trial, it is admitted that the NIR stent meets each limitation of claim 23 of the '762 patent, either literally or under the doctrine of equivalents, except for the 'substantially uniform thickness' limitation." D.I. 1310 Tab 1 at 2.

It would have been perfectly appropriate to tell the jury the true fact – that BSC ***admitted*** for purposes of this trial that the NIR stent infringes "wall surface" and every other limitation of claim 23 aside from "substantially uniform thickness." It was equally appropriate to give the more neutral instruction that the Court in fact delivered.

2. BSC Has Withdrawn Its Argument Relating to the Retention of the Court's Response to the Note from the Jury

Following the Court's letter of April 29, 2005 (D.I. 1402), BSC has withdrawn its assertion that the alleged failure "to keep a record of the Court's *ex parte* communication with the jury" was "prejudicial error that warrants a new trial." D.I. 1395 at 21. That argument accordingly does not merit further discussion.

3. References to Deposition Testimony by BSC Witnesses Do Not Require a New Trial

BSC misses the mark when it argues (D.I. 1395 at 22-26) that it was prejudiced by references in closing arguments to the deposition testimony of BSC engineer Brian Brown and BSC expert Dr. Reginald Low.

Contrary to BSC's contention (D.I. 1395 at 23), Mr. Brown's testimony was "admitted as substantive evidence." That testimony was offered as a party admission, and it was admitted on that basis. 3/22/05 Tr. 863:6-24; 3/22/05 Tr. 975:17-976:5. That was perfectly appropriate under Fed. R. Evid. 801(d)(2)(D). As the Court stated in allowing this evidence: "[G]enerally, employees of a party, their testimony is deemed admissions of a party ..." 3/22/05 Tr. 863:21-24. With Mr. Brown's testimony having been admitted in evidence as an admission, it was appropriate for Cordis to display that testimony to the jury, 3/22/05 Tr. 863:6-24; 3/22/05 Tr. 975:17-976:5, and comment on it in closing arguments.

BSC misreads Fed. R. Evid. 801(d)(2)(D) when it argues (D.I. 1395 at 22) that Mr. Brown's testimony cannot qualify as a party admission because he is not an officer, director or managing agent of BSC. Rule 801(d)(2)(D) has a broader scope. Under the express terms of that Rule, "statement[s] by [a] party's agent or servant concerning a matter within the scope of the agency or employment, made during the existence of the relationship," are admissible as party admissions. Mr. Brown did not need to be an officer, director or managing agent for his statements to be admissible as admissions under Rule 801(d)(2)(D). See Lippay v. Christos, 996 F.2d 1490, 1497 (3d Cir. 1993); Big Apple BMW, Inc. v. BMW of N. Am., Inc., 974 F.2d 1358, 1372 (3d Cir. 1992); Zipf v. American Tel. & Tel. Co., 799 F.2d 889, 895 & n.8 (3d Cir. 1986); Moran v. Pittsburgh-Des-Moines Steel Co., 183 F.2d 467 (3d Cir. 1950).

The fact that Mr. Brown's admissions were made under oath in a deposition with BSC's counsel present does not make them less admissible under Rule 801(d)(2)(D). See, e.g., Tracinda Corp. v. DaimlerChrysler AG, 2005 WL 730322 (D. Del. Mar. 30, 2005) (Ex. A hereto). Contrary to BSC's contention, Fed. R. Civ. P. 32(a) does not impose additional requirements for the introduction of such admissions. Where, as here, "[deposition] excerpts fall

within [Fed. R. Evid. 801(d)(2)(C) or (D)] they are not hearsay and Fed. R. Civ. P. 32 has no application to their admissibility." Coleman v. Wilson, 912 F. Supp. 1282, 1295 (E.D. Cal. 1995) See also Angelo v. Armstrong Indus., Inc., 11 F.3d 957, 962-63 (10th Cir. 1993); Globe Savings Bank, F.S.B. v. United States, 61 Fed. Cl. 91, 96 (Ct. Cl. 2004) ("Fed. R. Evid. 801(d)(2)(D) and [Rule] 32(a) regulate the admissibility of depositions in different ways by allowing admission in differing circumstances") (collecting cases). There was no error in admitting Mr. Brown's testimony under Fed. R. Evid. 801(d)(2)(D), and there was no impropriety in counsel's reference to that evidence in closing argument.

In any event, Mr. Brown's testimony – that "the thickness [of the NIR of the metal cross-section] is "a constant" throughout the stent and that "the entire [NIR] stent is the same thickness," 3/23/05 Tr. 1214:22-1216:6 – was consistent with, and thus cumulative of, measurements by BSC engineers showing a miniscule standard deviation of only six hundred-thousandths of an inch (0.00006 inch) from an otherwise uniform "wall thickness." 3/18/05 Tr. 440:6-442:9; see also PX 7236. It also was cumulative of admissions of BSC's expert Dr. Richter, that "the metal is what defines the [stent's] wall," 3/22/05 Tr. 848:17-22; that the metal sheet used to make the NIR has a "uniform thickness," 3/22/05 Tr. 851:4-7; and that the thickness of the metal "stays the same" and thus is as uniform in the final product as in the flat sheet. 3/22/05 Tr. 851:4-18.

Similarly, BSC argues that it was prejudiced by the reference in closing argument to deposition testimony by its medical expert Dr. Low stating that he understood the "thickness of the wall of a stent" to mean "the thickness of the metal from which it was constructed." 3/23/05 Tr. 1222:20-1223:4. Dr. Snyder was cross-examined about this testimony and it was part of the record. As such, it was permissible to refer to that testimony in closing arguments.

See 3/23/05 Tr. 1231:11-12. In any event, the testimony in question was cumulative of the admission of Dr. Richter that "the metal is what defines the [stent's] wall," 3/22/05 Tr. 848:17-22, and the reference to it did not prejudice BSC.

4. The Infringement Verdict is Not Against the Weight of the Evidence

BSC's final argument is a perfunctory assertion that the infringement verdict was against the weight of the evidence. As discussed in Point I(A), supra, the verdict was supported by overwhelming evidence. There is no basis for a new trial on infringement of claim 23.

II. VALIDITY

A. BSC's Motion for JMOL on Validity

1. Substantial Evidence Supports the Jury's Finding that BSC Failed to Meet its Burden of Proving Invalidity by Clear and Convincing Evidence

In moving for JMOL on obviousness, BSC faces a heavy burden. "'Where ... a jury finds a patent valid, [courts should] not disturb that finding unless reasonable jurors could not have reached that verdict.'" Junker v. Eddings, 396 F.3d 1359, 1364-65 (Fed. Cir. 2005), quoting Door-Master Corp. v. Yorktowne, Inc., 256 F.3d 1308, 1312 (Fed. Cir. 2001).

The BSC verdict was the third time a fact-finder rejected an obviousness challenge to claim 23 based on Ersek. The first time was in 2003, in the Cordis v. ACS arbitration, when a panel of experienced patent arbitrators rejected the same obviousness argument after a two-week evidentiary hearing. The second time was in early March 2005, when the AVE jury also rejected an obviousness challenge to claim 23. These decisions are a ""red flag' warning'" against this Court "reaching a contrary legal conclusion." Mendenhall v. Cedarapids, Inc., 5 F.3d 1557, 1569 (Fed. Cir. 1993) (citation omitted).

Substantial record evidence supports the jury's verdict that BSC failed to meet its burden of proving obviousness by clear and convincing evidence.

Consistent with settled law, the jury was properly instructed that in determining the "scope and content of the prior art" it needed to consider art that was "reasonably pertinent to the particular problem with which the inventor was faced." 3/23/05 Tr. 1356:15-25. See In re Paulsen, 30 F.3d 1475, 1481 (Fed. Cir. 1994). Ersek does not fall within that category. As Dr. Buller testified, the Ersek '744 patent addresses an entirely different problem and comes from an entirely different field of art. Ersek teaches "a surgical operative tool" that can be used to "speed up" the time for conventional, open surgical procedures. 3/18/05 Tr. 500:7-9. The Ersek tool is a staple-like device that permits "instant and positive fixation" (PX 95 at col. 1:54-55), to "replace the surgeon's sutures." 3/18/05 Tr. 494:1-15; see also 3/18/05 Tr. 494:16-495:22. This "has nothing to do with Dr. Palmaz's invention. This is in a completely different art." 3/18/05 Tr. 494:12-14.

Based on this evidence, a reasonable jury was entitled to find that the Ersek reference was not "reasonably pertinent to the particular problem with which the inventor was faced." That alone is sufficient to support the verdict on obviousness. Gagliardo, 311 F. 3d at 568; Arthrocare, 310 F. Supp. 2d at 652. But there is much more.

In order to make Ersek appear similar to claim 23, BSC ignored the invention and denigrated claim 23 as covering "an expandable metal tube." Thus, BSC's counsel told the jury in his closing argument that "an expandable metal tube is something that Dr. Palmaz did not invent." 3/23/05 Tr. 1236:13-14.

Everyone agrees that Dr. Palmaz "didn't invent tubes" and "didn't invent slots." 3/18/05 Tr. 466:15-23. But claim 23 cannot be trivialized in that fashion. By its express terms,

Claim 23 is directed at a particular kind of medical device – "[a]n expandable intraluminal vascular graft," with a first diameter that "permits intraluminal delivery …." PX 3 at 11:62, 12:3-5. The specification explains that "intraluminal vascular grafts" for "intraluminal delivery" are an alternative to – and different from – devices for conventional open surgery. The very first substantive sentence in the specification makes this clear (id. at 1:19-25):

> The invention relates to an expandable intraluminal graft for use within a body passageway or duct and, more particularly, expandable intraluminal vascular grafts which are particularly useful for repairing blood vessels narrowed or occluded by disease ….

The next sentence explains the meaning of "intraluminal endovascular grafting" (id. at 1:28-37):

> Intraluminal endovascular grafting has been demonstrated by experimentation to present a possible alternative to conventional vascular surgery. Intraluminal endovascular grafting involves the percutaneous insertion into a blood vessel of a tubular prosthetic graft and its delivery via catheter to the desired location within the vascular system. Advantages of this method over conventional vascular surgery include obviating the need for surgically exposing, incising, removing, replacing or bypassing the defective blood vessel.

Unlike the "expandable intraluminal vascular graft" of claim 23, the Ersek device is "a surgical device to be used in a major surgical operation with a patient opened up. This had nothing to do with intraluminal delivery." 3/18/05 Tr. 493:8-10; see also 3/18/05 Tr. 500:5-12, 501:24-502:11, 505:21-506:5, 507:15-508:6.

BSC argues (D.I. 1395 at 27) that claim 23's use of the phrase an "expandable intraluminal vascular graft" is not limiting and must be disregarded in considering the differences between claim 23 and Ersek. Controlling authority compels the opposite conclusion.

"No litmus test defines when a preamble limits claim scope." In re Cruciferous Sprout Litig., 301 F.3d 1343, 1347 (Fed. Cir. 2002). Determining whether a preamble is limiting requires "'[a] review of the entirety of the patent to gain an understanding of what the inventors

actually invented and intended to encompass by the claim.'" Id., quoting Corning Glass Works, Inc. v. Sumitomo Elec., USA, Inc., 868 F.2d 1251, 1257 (Fed. Cir. 1989). The Federal Circuit has treated preamble language as limiting where, as here, the specification uses the same language in describing "a key benefit," Storage Tech. Corp. v. Cisco Sys., Inc., 329 F.3d 823, 834 (Fed. Cir. 2003), or a "stated object of the invention," Cruciferous Sprout, 301 F.3d at 1347; where the patentee used the same language in "the title of the patent itself and the 'Summary of the Invention,'" Poly-America, L.P. v. GSE Lining Tech., Inc., 383 F.3d 1303, 1310 (Fed. Cir. 2004); where the text of the preamble is "intimately meshed with the ensuing language in the claim," Pitney-Bowes, Co. v. Hewlett-Packard, Inc., 182 F.3d 1298, 1306 (Fed. Cir. 1999); or where the preamble otherwise is "'necessary to give life, meaning, and vitality' to the claim." Cruciferous Sprout, 301 F.3d at 1347 (citation omitted).

These factors are present here. The '762 specification "is replete with references to the invention as [an expandable intraluminal vascular graft], including the title of the patent itself and the 'Summary of the Invention.'" Poly-America, 383 F.3d at 1310. See, e.g., PX 3 at 1:27-34, 3:6-29, 3:32-34, 4:62-68, 5:43-55; 6:9-13. The specification uses the phrase "expandable vascular intraluminal graft" in describing "key benefit[s]," Storage Tech., 329 F.3d at 834, and "stated object[s], Cruciferous Sprout, 301 F.3d at 1347, of the invention. See, e.g., PX 3 at 3:6-34. This phrase is "intimately meshed with the ensuing language in the claim," Pitney-Bowes, 182 F.3d at 1306, including the limitation reciting "a first diameter which permits intraluminal delivery."

The preamble accordingly should appropriately be treated as a limitation of claim 23. See, e.g., Cruciferous Sprout, 301 F.3d at 1347; Poly-America, 383 F.3d at 1310; Storage Tech., 329 F.3d at 834; Corning Glass, 868 F.2d at 1257. This Court previously recognized that

the preamble is limiting when it construed the term "graft" to mean a device "capable of serv[ing] to prevent a body passageway from collapsing ...." D.I. 461 [6/18/99 Mem. Op.] at 14. BSC's approach, of disregarding the preamble, would treat claim 23 "indiscriminately," Corning Glass Works, 868 F.2d at 1257, as covering conventional open surgery devices that are not "expandable intraluminal vascular grafts." That approach is unconnected to Dr. Palmaz's invention and is "divorced from reality." Id.

BSC's argument is untimely, as well as incorrect. BSC could have asked for a construction of the preamble (as limiting or non-limiting) in its Markman submissions. It did not do so then, or at any other time in the seven years prior to the recent retrial. It should not be heard to raise the issue after a second jury has reached a verdict in Cordis' favor.

Moreover, the preamble is not the only portion of claim 23 that requires a device capable of intraluminal delivery. The claim also requires a first diameter "which permits intraluminal delivery ... into a body passageway having a lumen." PX 3 at 12:3-5. Cordis relied on this limitation during prosecution when it distinguished Ersek as lacking a "a first diameter which permits intraluminal delivery." PX 13 at PWRAP 3055-56, 3061, 3-83-84. See Hoffer v. Microsoft Corp., --- F.3d ---, 2005 WL 927148 at *3 (Fed. Cir. April 22, 2005) (Ex. B hereto).

Moreover, the preamble was only one of many significant differences between Ersek and claim 23. BSC tried to pass off those differences as "very, very minor," with only a "[s]light difference in smoothness, slight difference in uniform thickness, slight difference in wall surface ...." 3/23/05 Tr. 1276:18-24 (BSC closing argument). But as Dr. Buller testified, the differences are pervasive and significant:

- Ersek does not have a "wall surface" disposed in a "common cylindrical plane" as required by claim 23. Instead, as shown in Fig. 5 of the Ersek

patent, "it has a saw-tooth cross-section, and it is not lying on a common cylindrical plane." 3/18/05 Tr. 502:12-19.

- Ersek does not have a "substantially uniform thickness" as required by claim 23. As shown in Fig. 5, Ersek has systematic variations in thickness of 100%, with "bridge" regions that have "twice the thickness" of the strands. 3/18/05 Tr. 502:20-503:5. That is not a "substantially uniform thickness" under the Court's claim construction. See 3/18/05 Tr. 510:21-511:1.

- Ersek does not have a "first diameter which permits intraluminal delivery" as required by claim 23. Intraluminal delivery is "used in the art for delivery along a body passageway [while] avoiding surgery"; "Ersek is the antithesis of that." 3/18/05 Tr. 503:6-15; see also 3/18/05 Tr. 508:7-509:14. Ersek's narrow outwardly projecting edges make it unsuitable for intraluminal delivery. 3/18/05 Tr. 508:7-12.

- Ersek does not have a "second, expanded and deformed diameter … which is variable and dependent upon the amount of force" as required by claim 23. Instead, the Ersek device "increases [in] diameter [only at] two points" and remains unexpanded between those two points – and even that selective increase in its width happens "by a single stroke of [his] device" and is "not controllable." 3/18/05 Tr. 503:18-504:7.

- Ersek does not teach the use of the device to "expand the lumen of body passageway" as recited in claim 23. Indeed, "[t]here is no teaching in Ersek of

expanding the lumen, of using it to treat an area of narrowing." 3/18/05 Tr. 504:8-16; see also 3/18/05 Tr. 506:6-18.

- Ersek lacks a "smooth surface" in the first diameter as required by claim 23. "Ersek is the antithesis of smooth. Ersek has a multitude of outwardly projecting edges." 3/18/05 Tr. 504:17-22; see also 3/18/05 Tr. 506:19-507:8. In allowing claim 23 without amendment in the '762 reexamination, the Patent Office agreed that the "wall surface of the Ersek fixation sleeve includes a multitude of … obstacles, (one at each bridge), making it rough rather than smooth. Therefore, the Ersek reference fails to meet the 'smooth surface' limitation …." PX 14 at PWRAP 3257; see also 3/18/05 Tr. 511:2-13.

At trial, BSC asserted that it would have been possible to alter the Ersek device to reduce the differences between Ersek and claim 23. Thus, BSC's counsel told the jury in closing arguments that it would be possible to "flatten" the Ersek device "if you want to use it for transluminal delivery." 3/23/05 Tr. 1276:18-1277:5 (closing argument). But as the Court properly instructed the jury, "the mere fact that the prior art can be modified does not make the modification obvious unless the prior art suggest[ed] the desirability of the modification." 3/23/05 Tr. 1359:1-4. See In re Fritch, 972 F.2d 1260, 1266 (Fed. Cir. 1992); In re Laskowski, 871 F.2d 115, 117 (Fed. Cir. 1989). Without hindsight knowledge of Dr. Palmaz's invention, there was no motivation to deliver the Ersek device intraluminally or otherwise alter it to make it more like Palmaz. As Dr. Buller testified, Ersek and devices for intraluminal delivery are completely different fields of art. 3/18/05 Tr. 494:12-14.

Indeed, flattening Ersek's outwardly projecting edges, as urged by BSC's counsel, would defeat the basic purpose of the Ersek device. As Dr. Buller explained, "if you take them

away [Ersek's outwardly projecting edges] and flatten or smooth those, you've taken away the whole purpose of Ersek of having this multitude of outwardly projecting edges" as a substitute for sutures. 3/18/05 Tr. 511:15-19. There was no motivation in the art to alter Ersek in a way that would defeat its intended purpose.

Based on the evidence presented, a reasonable jury could conclude that the differences between Ersek and claim 23 were numerous and significant, and that a person of ordinary skill would not have had any motivation to modify Ersek to deliver it intraluminally or otherwise make it more like Palmaz. Gagliardo, 311 F.3d at 568; Arthrocare, 310 F. Supp. 2d at 652.

Certainly, the Patent Office did not view Ersek as invalidating prior art. The Examiner carefully considered Ersek in the '762 reexamination, and concluded that "None of the references of record" – including Ersek – could properly be used to reject claim 23. PX 14 at PWRAP 3260 (emphasis in original); see also 3/18/05 Tr. 475:21-476:19; 3/18/05 Tr. 511:20-513:22. Based on the record evidence, a reasonable jury was entitled to agree. Gagliardo, 311 F.3d at 568; Arthrocare, 310 F. Supp. 2d at 652.

Secondary considerations provided added support for the jury's verdict, if any were needed. The Court properly instructed the jury that it was required to consider relevant "objective evidence," if any, in deciding the issue of obviousness. 3/23/05 Tr. 1357:23-25, 1356:8-9. That evidence included the following:

- Long-felt need: Prior to Dr. Palmaz's invention, the main treatment for coronary artery disease was balloon angioplasty. Angioplasty had well-known drawbacks. One frequent disadvantage was tearing of the blood vessel ("dissection"), which could require emergency open-heart surgery or cause a

heart attack. Another drawback included high rates of re-narrowing ("restenosis"). 3/17/05 Tr. 157:20-162:9 (Fischell); 3/18/05 Tr. 375:5-376:4 (Buller). Doctors were well-aware of these problems, and were working to find a better solution. 3/17/05 Tr. 162:10-163:2; 3/18/05 Tr. 376:2-4.

- Failure by others: Because angioplasty's drawbacks were serious and well-known, many of the best minds in medicine were trying to find a better treatment. Most of the ideas they considered – hot tip lasers, pyroplasty, atherectomy and so on – turned out to be dead ends. None of them provided safer or better long-term results that angioplasty. 3/17/05 Tr. 162:14-163:2; 3/18/05 Tr. 376:5-380:13; PX 188. Dr. Palmaz's invention succeeded where others failed.

- Skepticism: In the 1980s, there was great skepticism about leaving prosthetic devices in the coronary arteries. 3/18/05 Tr. 381:2-384:2. That skepticism was heightened by a "major medical disaster," the Shiley heart valve, which had a tendency to fracture and caused numerous deaths. 3/18/05 Tr. 382:13-25. Concern about leaving prosthetic devices in the coronary arteries caused various companies, including Shiley, to reject Dr. Palmaz's concept as too risky. 3/1/05 Tr. 215:17-216:1 (Palmaz); 3/18/05 Tr. 383:1-384:2 (Buller); PX 3658.

- Commercial success: Clinical studies proved the skeptics wrong. The results of the Stress and Benestent studies, published as the lead articles in the *New England Journal of Medicine* in August 1994, showed that the Palmaz-Schatz stent is safe, effective and superior to balloon angioplasty. The Palmaz-

Schatz stent was launched soon after the publication of the study results. It was an immediate success, with sales of $800 million in its first two full years on the market. 3/18/05 Tr. 318:18-319:11 (Croce). In 1997, the medical device industry voted the Palmaz-Schatz stent the most successful new product launch in the prior 15 years. 3/18/05 Tr. 322:12-323:1. More recent Cordis stents practicing the '762 invention also have enjoyed considerable commercial success. Total combined sales of Cordis' Palmaz-Schatz, BX Velocity and Cypher stents come to approximately $4.5 billion. 3/18/05 Tr. 327:1-25; 3/18/05 Tr. 540:10-542:8 (Buller). All if these products use the '762 invention. Id.

- Praise for the invention: There has been "enormous praise for Dr. Palmaz's invention …." 3/18/05 Tr. 542:9-22. No device in the past 25 years has had a greater impact on the treatment of coronary artery disease. 3/17/05 Tr. 173:11-21. Dr. Palmaz has received numerous awards for his contributions to medicine, including awards from the American Heart Association, the Society of Interventional Radiologists, TransCather Therapeutics (TCT, the most important cardiovascular meeting in the world), the International Society of Endovascular Surgery (PX 7618), the Thorax Center, and the International Society of Endovascular Therapy (PX 7611). 3/17/05 Tr. 231:20-236:24. Palmaz stents are in the Smithsonian Institute in Washington, D.C. 3/17/05 Tr. 236:25-237:12. The record even includes praise for the invention from one of the defendants, Scimed. 3/18/05 Tr. 543:5-15, PX 3768.

- Licenses under the patent: Other companies, including Abbott Laboratories, have taken licenses in the '762 patent. 3/18/05 Tr. 330:13-331-3.

At trial, BSC had no real response to this evidence. Its expert Dr. Richter was of two minds about Dr. Palmaz's contributions. On the one hand, he praised the Palmaz-Schatz stent as a "pioneering device," 3/21/05 Tr. 757:25-758:8, and praised Dr. Palmaz as a "pioneer[]" who (along with Dr. Gianturco) "enabled this whole field." Id. But he then retreated and offered faint praise for Dr. Palmaz's perseverance in promoting a minor advance. 3/21/05 Tr. 758:9-20. As Dr. Richter put it, "the smaller the invention, the more impressive is the way [Dr. Palmaz] was able to push it forward." Id. A reasonable jury was entitled to find this testimony offensive, rather than credible.

BSC's engineering expert Dr. Snyder was equally dismissive. Instead of acknowledging that Dr. Palmaz has received numerous awards for his contributions to medicine, Dr. Snyder belittled the awards as a tribute to Dr. Palmaz's "energy and enthusiasm." 3/22/05 Tr. 958:21-959:8. In the same vein, Dr. Snyder discounted the decision of the Smithsonian Institution to display the Palmaz stent as "a testament to somebody who worked so hard." 3/22/05 Tr. 1073:17-24. When asked on cross-examination about the Innovators Award that Dr. Palmaz received from the International Society of Endovascular Engineers, Dr. Snyder's response was that he "didn't consider parties." 3/22/05 Tr. 1076:4-10. As with Dr. Richter's testimony, a reasonable jury was entitled to find this testimony offensive, rather than credible.

When the evidence is viewed "in the light most favorable to the [verdict winner]," and the verdict winner is given "the advantage of every fair and reasonable inference," Gagliardo, 311 F. 3d at 568, a reasonable jury could find that the evidence of secondary considerations – standing alone – was strong enough to preclude a finding of obviousness.

As it did at trial, BSC discounts the overwhelming secondary considerations as relating in large part to the "stent-balloon combination" – as if that were not covered by claim 23. However, the balloon-stent combination is well within the scope of claim 23. Claim 23 requires that the stent achieve its "second, expanded diameter" by "the application from the interior of the tubular member of a radially, outwardly extending force," PX 3 at 12:7-9, e.g., by expansion of a balloon, as described in the '762 specification. Id. at 9:14-20, 9:50-58, 10:11-17. Use of a balloon to achieve the second, expanded diameter is the preferred embodiment that is contemplated by the specification and it is squarely covered by claim 23.

Contrary to BSC's contention, the evidence showed a direct relation between the secondary considerations and claim 23. The stent of claim 23 initially was met with skepticism, but eventually succeeded where others failed in satisfying the long-felt need for an alternative to angioplasty. The stent of claim 23 has received widespread praise from medical societies and the medical device industry. Stents covered by claim 23 have enjoyed enormous commercial success and compete in what is now a $3 billion industry. Stents covered by claim 23 are in the Smithsonian Institution because of the significance of their contribution to medicine.

"Viewing the evidence in the light most favorable to the [verdict winner] and giving it the advantage of every fair and reasonable inference," Gagliardo, 311 F. 3d at 568, there was ample evidence from which a reasonable jury could find that claim 23 is nonobvious and BSC had not met its burden of proving otherwise by clear and convincing evidence. There is no basis for overturning that verdict.

B. BSC's Motion for a New Trial on Validity

BSC received a fair trial on validity, as well as on infringement. Once again, it cannot show that there would be a "'miscarriage of justice ... if the verdict were to stand.'"

Olefins, 9 F.3d at 289-90, quoting Fineman, 980 F.2d at 211. Its new trial motion has should be denied.

1. Exclusion of Evidence Comparing Claim 23 to Other Claims Not Being Asserted was Not Prejudicial Error

BSC argues (D.I. 1395 at 33-36) that the exclusion of comparisons between claim 23 and other claims that are not being asserted in this case was prejudicial error. But the Court was correct in excluding such comparisons. Evidence about unasserted claims would have caused confusion that far outweighed its negligible probative value. The Court properly weighed the relevant factors under Fed. R. Evid. 403 in excluding this evidence.

2. Exclusion of "Project Olive" Evidence About the NIR's Flexibility Was Not Prejudicial Error

After introducing extensive evidence about the NIR's flexibility, BSC has the audacity to argue (D.I. 1395 at 33-36) that the exclusion of additional "Project Olive" evidence on the same subject was prejudicial error. Further evidence on the NIR's flexibility would only have been cumulative, and the prejudice caused by "Project Olive" evidence would have far outweighed its nonexistent probative value.

As the Court commented during the trial, BSC spent "a lot of time" (3/21/05 Tr. 827:15-16) describing the NIR stent's desirable features. For example, Dr. Richter testified:

- Physicians consider flexibility to be one of the most "important attributes" of a good stent. 3/21/05 Tr. 760:20-761-24.

- In contrast to the NIR stent, the Palmaz-Schatz stent was relatively inflexible ("you would not be able to bend it"). 3/21/05 Tr. 762:11-18.

- Whereas the Palmaz-Schatz stent was capable of bending only at a single articulation point, the NIR stent "flexes uniformly … everywhere along the length of the stent ….." 3/21/05 Tr. 763:5-9; see also 3/21/05 Tr. 764:3-14.

- The Palmaz-Schatz stent could not be used in long lengths because it was so inflexible, but the uniform flexibility of the NIR allows it to be sold in "very long stent[s]" of up to 30 millimeters. 3/21/05 Tr. 764:15-22. "In the Palmaz/Schatz-like configuration, no such long stents were available because you couldn't use them." Id.

- The NIR's superior flexibility is attributable to its "flexible closed cell geometry." 3/21/05 Tr. 763:1-5; see also 3/21/05 Tr. 765:14-767:2.

- The design of the NIR contributes to flexibility by allowing the connectors on the outside of a curve to lengthen and the connectors on the inside of the curve to shorten. 3/21/05 Tr. 762:19-23; 3/21/05 Tr. 765:14-767:2.

- Because of its desirable features, the NIR stent "was received by cardiologists with great enthusiasm" when it was introduced. 3/21/05 Tr. 813:17-23.

BSC's counsel argued during the trial – as BSC argues now – that it needed to address these issues in response to Cordis' proof that all successful stents practice Dr. Palmaz's invention. That assertion was met with well-deserved incredulity (3/21/05 Tr. 827:7-18):

> MR. BADENOCH [BSC's counsel]: …. [T]he reason we're also explaining a little bit about the NIR is something that –
>
> THE COURT: A little bit about the NIR?
>
> MR. BADENOCH: … They started … the drum beat, your Honor, of saying every stent second generation, third generation, all the platforms, use the Palmaz invention, use the Palmaz ring.

> THE COURT: There's no question in my mind that you've spent a lot of time on the NIR. You always intended to spend a lot of time on the NIR. So don't, please don't insult my intelligence with that argument.

These comments are equally applicable to BSC's current argument.

In addition to being cumulative of Dr. Richter's lengthy testimony, "Project Olive" evidence carried a potential for prejudice and confusion that outweighed its probative value. As Cordis explained in its Motion *In Limine* No. 13 (D.I. 1292), BSC used Project Olive evidence in the trial in 2000 to argue that the NIR was not "equivalent" to the stent of claim 23. For example, BSC's counsel argued in 2000: "If [the NIR] was equivalent, would they be thinking about ... spending 325 million for something that's equivalent to what they already had?" D.I. 203 at Tr. 2675:10-13. Whatever relevance Project Olive may have had in 2000 no longer existed in the retrial because there was no assertion of infringement under the DOE.

The Court properly balanced the probative value of Project Olive evidence against its potential for confusion and prejudice. The exclusion of such evidence under Fed. R. Evid. 403 was appropriate, and did not prejudice BSC.

3. Descriptions of the Ersek '744 Patent by Dr. Ersek and by Dr. Heuser were Fair Grounds for Cross-Examination of BSC's Validity Expert

BSC also argues that it was prejudiced when the Court allowed Cordis to cross-examine its expert about characterizations of the Ersek device by Dr. Ersek and by a leading cardiologist, Dr. Richard Heuser, and by a brief reference to that testimony in closing arguments. Again, the record refutes BSC's position.

At trial, the parties disputed whether the Ersek device could be characterized as "staple-like." Dr. Buller testified that the Ersek device could "fairly [be] call[ed] a stapling device" because of its "a multitude of narrow projecting edges, which act as a stapler." 3/18/05

Tr. 498:1-16. Dr. Snyder derided this testimony as "ridiculous," and insisted that it would be wrong to characterize the Ersek device as staple-like. 3/22/05 Tr. 899:2-25; 3/22/05 Tr. 945:5-6, 3/22/05 Tr. 945:19-947:9, 3/22/05 Tr. 1038:3-5.

In view of Dr. Snyder's testimony, it was fair grounds for cross-examination to ask Dr. Snyder whether he agreed with Dr. Ersek's publicly available characterization of the device of his '744 patent as a "staple-like device," see D.I. 1395, BSC Br. Ex. F at 14; 3/22/05 Tr. 1058:7-1059:8, and to ask whether he agreed with testimony by Dr. Richard Heuser, a leading cardiologist, that the Ersek device was staple-like. 3/22/05 Tr. 1059:13-1060:21.

Before allowing this line of questioning, the Court stated that "[y]ou can impeach an expert with anything," and BSC's agreed. 3/22/05 Tr. 1053:5-9. The Court stated that Dr. Snyder's testimony had been "misleading" and ruled that these questions were "appropriate impeachment." 3/22/05 Tr. 1057:5-10. BSC offers nothing to call that conclusion into question.[1]

BSC also misses the mark when it complains about references to this impeachment testimony during closing argument. Prior to those arguments, the Court ruled – correctly and without disagreement from BSC – that impeachment testimony that was part of the record could be read, and presumably commented upon, during closing arguments. 3/23/05 Tr. 1230:20-1231:12. That ruling was correct, and BSC cannot seriously challenge it.

[1] BSC ignores the distinction between affirmative testimony and impeachment when it points out that Dr. Ersek was not allowed to testify as an expert under Daubert in the AVE trial and was not allowed to expand on the teachings of his own patent. The appropriate limits on Dr. Ersek's direct testimony in the AVE case have no bearing on permissible impeachment of an expert. As the Court commented during the trial, "an expert can be impeached by a rock, can be impeached by anything." 3/22/05 Tr. 1044:11-15. BSC has agreed. 3/22/05 Tr. 1053:5-9.

4. The Verdict on Validity is Not Against the Weight of the Evidence

Finally, BSC offers a perfunctory assertion that the verdict on validity was against the weight of the evidence. As discussed in Point II(A), supra, the verdict was supported by overwhelming evidence. There is no basis for a new trial on validity.

CONCLUSION

For the reasons set forth above, this Court should deny BSC's motions for JMOL or in the alternative a new trial.

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CERTIFICATE OF SERVICE

I hereby certify that on the 5th day of May, 2005, the attached **CORDIS' ANSWERING BRIEF IN OPPOSITION TO BSC'S MOTIONS FOR JMOL OR A NEW TRIAL ON INFRINGEMENT AND VALIDITY OF CLAIM 23 OF THE PALMAZ '762 PATENT** was served upon the following counsel of record in the manner indicated:

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